IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application Number	:	10/643,878	Confirmation No.: 5214
Applicant	:	Kevin T. FOLEY et al.	
Filed	:	August 20, 2003	
Title	:	SYSTEM AND METHOD FOR SECURING A PLATE TO THE SPINAL COLUMN	
TC/Art Unit	:	3731	
Examiner:	:	Daniel Jacob DAVIS	
Attorney Docket No.	:	64118.000036	
Customer No.	:	21967	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF JENNIFER JUNE UNDER 37 C.F.R. § 1.132

1. My name is Jennifer June. I am a United States citizen and reside at 3623 Galloway Avenue in Memphis, TN 38122.

2. Since 1999, I have been employed as a Marketing Specialist in the Marketing Communications Department of Medtronic Sofamor Danek ("Medtronic"), the assignee of the above-referenced patent application.

3. I have been informed that various claims of the above-referenced application have been rejected by the United States Patent & Trademark Office based on a Medtronic publication titled "Premier™ Anterior Cervical Plate System," by Thomas A. Zdeblick, M.D. and Harry N. Herkowitz, M.D., copyright 2000 (the "Premier publication"). The Premier publication is attached hereto as Exhibit A.

4. I have reviewed our publication records, and can confirm that the Premier publication was first published and made available to the public on or after October 1, 2000.

5. All statements made herein of my own knowledge are true, and all statements made on information and belief are believed to be true. These statements were made with the

knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

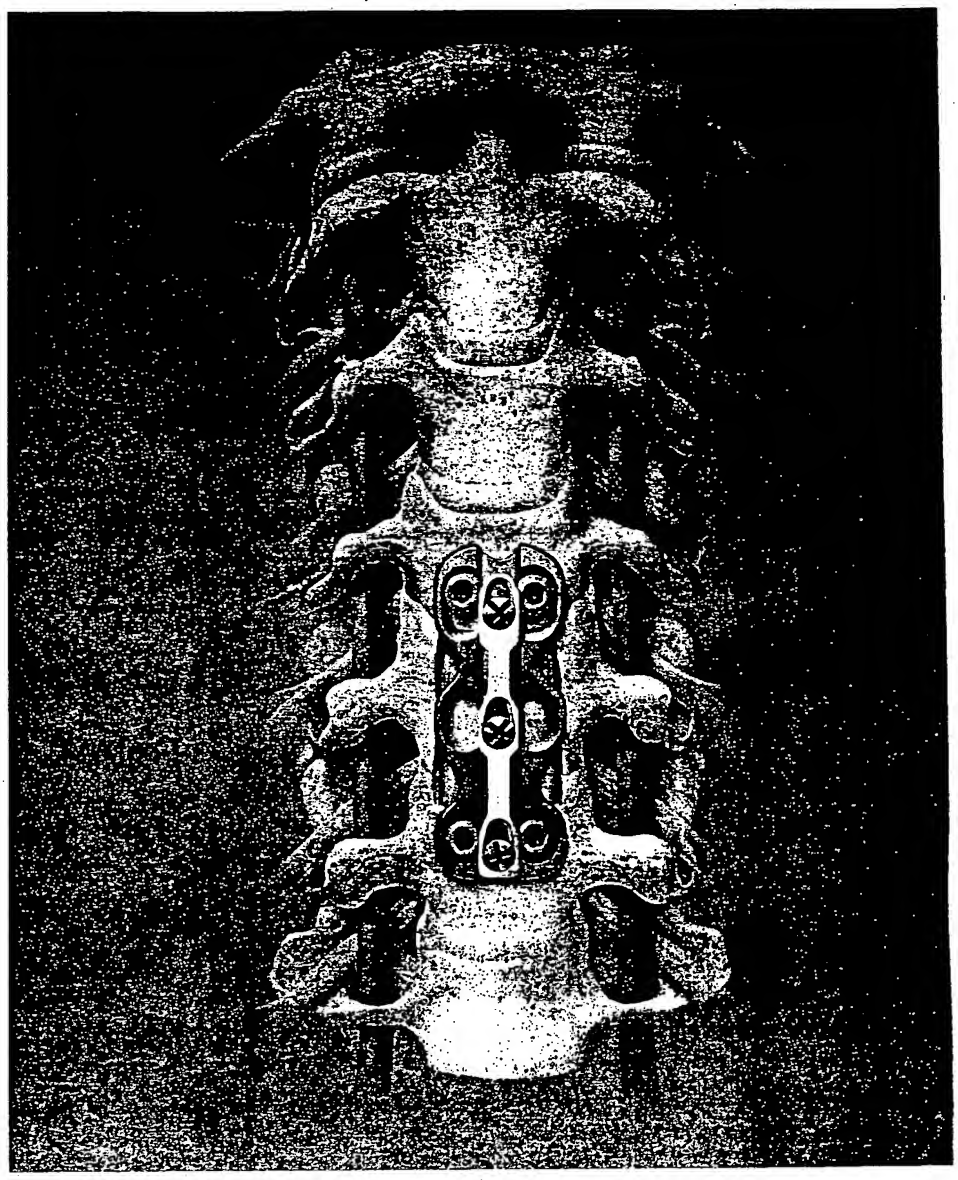
Date: 7-1-05

Jennifer June

Medtronic
SOFAMOR DANEK

PREMIER™ ANTERIOR CERVICAL PLATE SYSTEM

Surgical Technique



as described by:

Thomas A. Zdeblick, M.D.
University of Wisconsin
Madison, Wisconsin

Harry N. Herkowitz, M.D.
William Beaumont Hospital
Royal Oak, Michigan

Sample

TABLE OF CONTENTS

Multiple level ACDF (C4-C7)
Immediate post-op

Multiple level ACDF (C4-C7)
12 week follow-up

Axial Slots

Allow post-operative settling via axial screw translation.

Pre-Compression Techniques

Allow pre-compression of the graft construct to optimize fit and graft loading.

Attached Lock Mechanism

Sliding washer provides clearance for screw translation while providing a barrier to screw back out.

Superior Alignment Notch

Facilitates midline alignment of plate when utilized in conjunction with Compression Pin and Compression Sleeve.

Pre-Machined Lordotic Curve

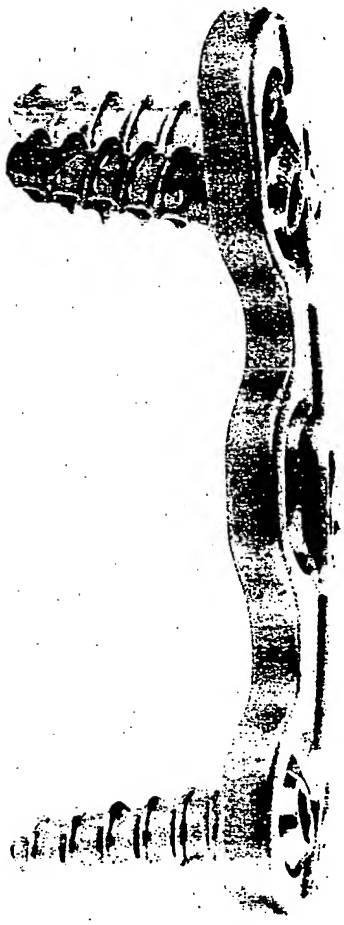
Accommodates normal anterior cervical lordosis.

Bone Screw Diameters 4.0/4.5mm

Allow surgeon maximum bone purchase.

Cancellous Thread Form

Reverse thread pattern enhances screw purchase pullout resistance.



Premier
ANTERIOR CERVICAL PLATE SYSTEM

PREMIER™ ANTERIOR CERVICAL PLATE SYSTEM

Dear Fellow Colleagues,

In recent years, semi-constrained plates have grown in popularity, due mainly to intraoperative flexibility in screw placement combined with the ability to allow for graft loading while incorporation progresses. The advantages of the PREMIER™ Anterior Cervical Plate System are to provide for axial load sharing of the graft during incorporation, and that pre-compression of the graft may be obtained both externally and internally during implantation. In addition, a unique lock washer system allows quick and easy implantation.

The PREMIER™ Anterior Cervical Plate System provides for axial load sharing via vertical screw translation along slots in the plate, while maintaining constrained fixation at the distal end of the construct, where loading is highest. The use of external graft pre-compression helps to secure the graft in an optimal position for healing. The internal pre-compression component provides graft pre-load which we believe accelerates healing.

The wide range of plate lengths available in the PREMIER™ Anterior Cervical Plate System accommodates the plating of single or multiple level anterior cervical fusions. Depending on the indication, internal and/or external pre-compression techniques may be applied to provide the same compression advantages to discectomy fusions as well as corpectomy struts. The unique attached bone screw locking mechanism ensures that screw back-out will not occur.

The PREMIER™ Anterior Cervical Plate System provides versatile, straightforward instrumentation, and features which will make the surgeon's experience as stress free as possible while providing the optimal environment for bony healing. In our hands, this has led to excellent clinical results.

The following monograph introduces the PREMIER™ Anterior Cervical Plate System, as well as many of our personal thoughts reflecting our current clinical practices and operative techniques.

Sincerely,

Thomas A. Zdeblick, M.D.
University of Wisconsin
Madison, Wisconsin

Harry N. Herkowitz, M.D.
William Beaumont Hospital
Royal Oak, Michigan

The patient is placed in the supine position with the head in slight extension. The posterior cervical spine may be supported to establish and maintain cervical lordosis. The surgeon must then choose a right- or left-sided approach. After this consideration, the head may be rotated to allow for adequate exposure of the cervical spine (*Figure 1*).

Typically a transverse skin incision is made. An avascular dissection plane is developed between the esophagus / trachea, medially, and the sternocleidomastoid / carotid sheath, laterally. Hand-held retractors may be utilized to provide initial exposure of the anterior vertebral column and the adjacent longus coli muscles (*Figure 2*).

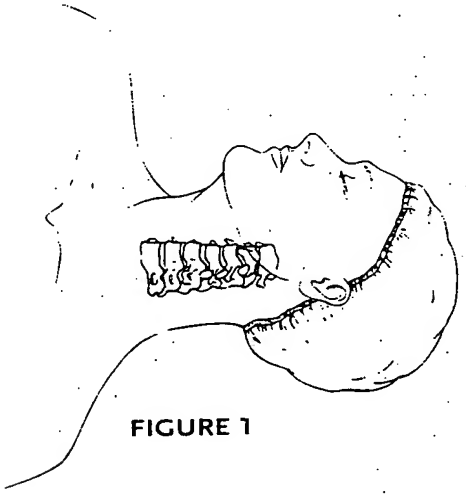


FIGURE 1

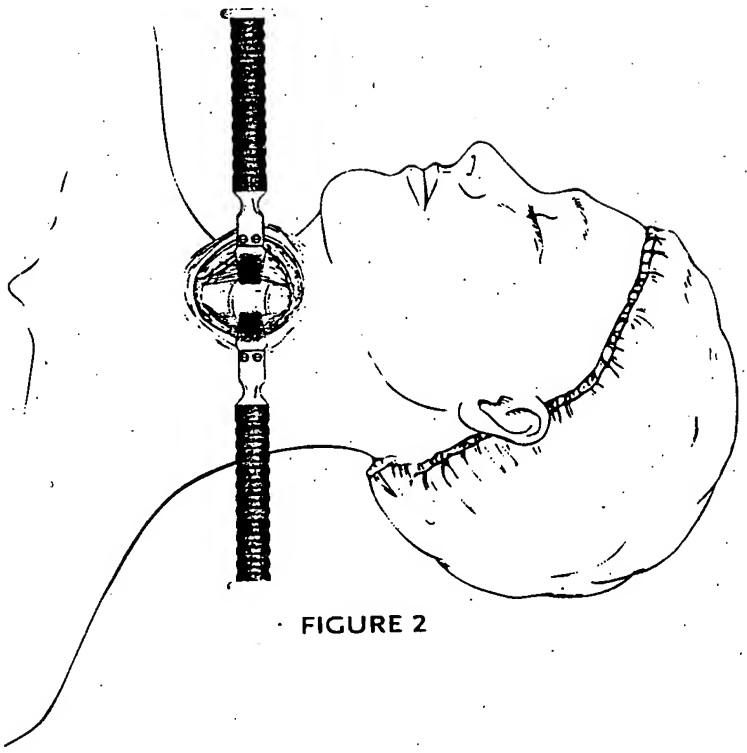


FIGURE 2

DISTRACTION ONLY

After the vertebral column has been exposed, the longus coli muscles are elevated and the "slotted foot" medial / lateral self-retaining retractor blades are securely positioned (*Figure 3*). Longitudinal retractors may be used to maximize the exposure *(Figure 4)*.

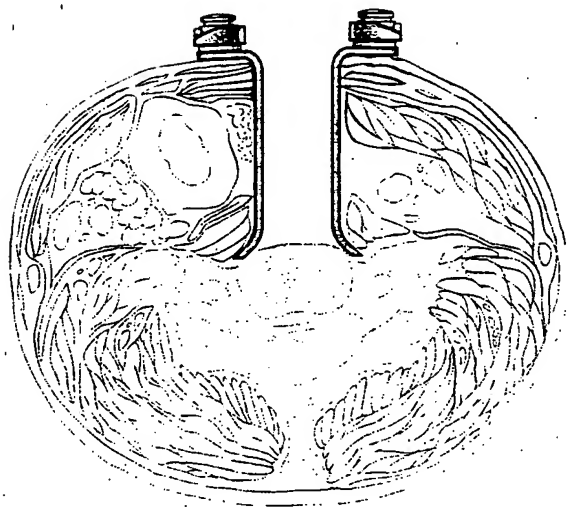


FIGURE 3

A vertebral body distractor may be used. The distraction pins are positioned midline in the vertebral bodies adjacent to the level to be treated (*Figure 5*). The distractor is placed over the pins and the appropriate amount of distraction is applied.

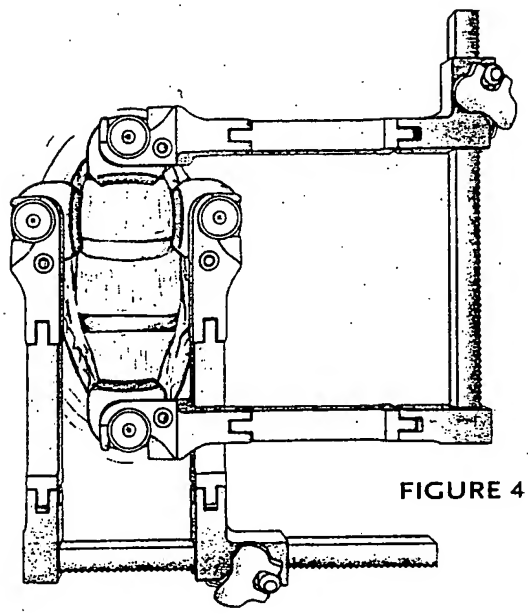


FIGURE 4

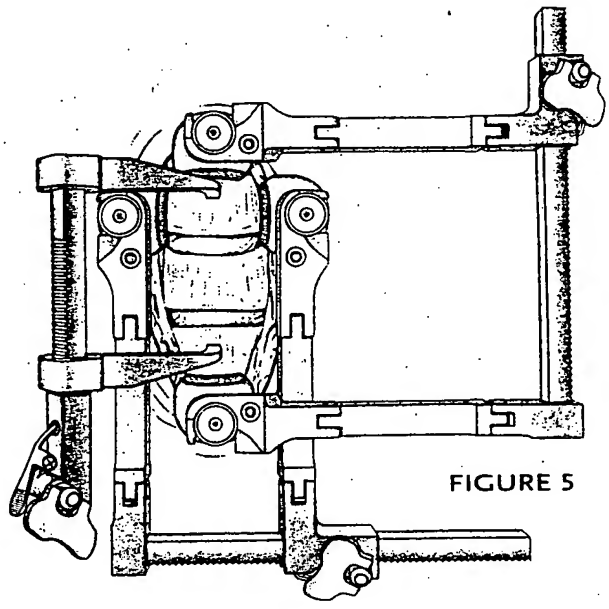


FIGURE 5

DISTRACTION WITH PLANNED EXTERNAL COMPRESSION

If the external compression technique is planned for later in the procedure, the Compression Pin Placement Template can be utilized. By placing the Compression Pin at this stage, it can be used as a distraction pin. This pin can be used in conjunction with a distraction pin for the distractor. Alternatively, two Compression Pins can be used for distraction. Use of the Template ensures proper location of the Compression Pin later in the procedure (*Figure 6*).

"The short height on the Compression pin provides flexibility in maintaining a minimal exposure, particularly in corpectomy cases."

– T. Zdeblick, M.D.

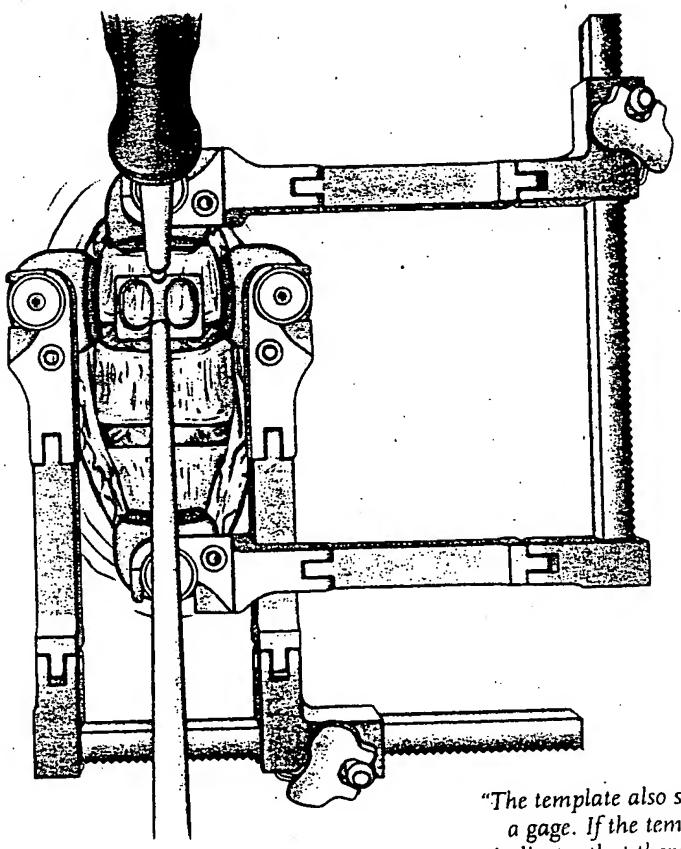


FIGURE 6

"It is helpful to remove any osteophytes from the endplate, and to smooth the superior endplate prior to using the template. The template references the edge of the endplate and subsequent tissue removal changes that reference."

– T. Zdeblick, M.D.

"The template also serves as a gage. If the template indicates that there is not adequate bone to place the pin, the anatomy is not suitable for external compression."

– H. Herkowitz, M.D.

Discectomies are completed at each level. Pituitaries, curettes, and kerrisons may be used to remove the disc material and cartilage to expose the posterior longitudinal ligament (*Figures 7 and 8*).

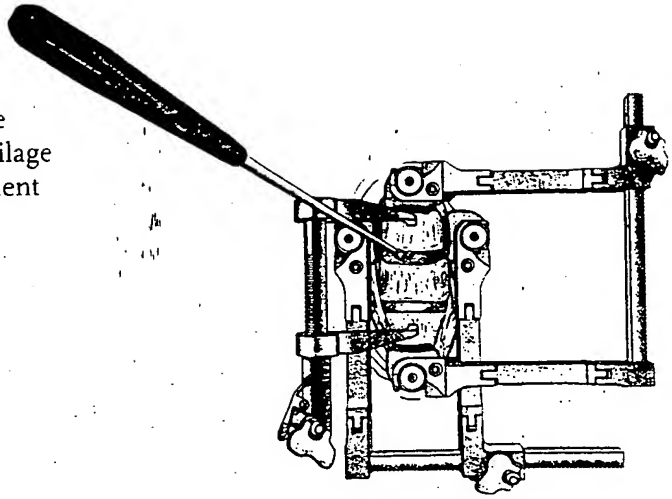


FIGURE 7

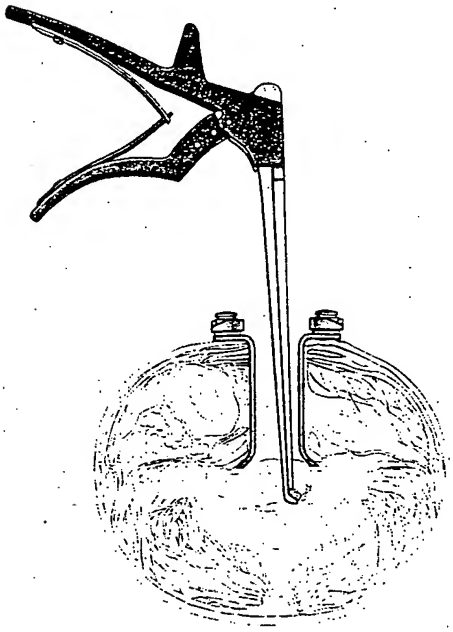


FIGURE 8

After the disc(s) have been removed, a corpectomy or partial corpectomy may be necessary to further decompress the spine. A rongeur may be used to remove a portion of the vertebrae. A high-speed drill with a large bore bur may be utilized to remove the remaining portion of the vertebrae (*Figure 9*). A curette is then used to carefully elevate the remaining bone anteriorly away from the dura, and a kerrison is used to clear the remaining bone and soft tissue.

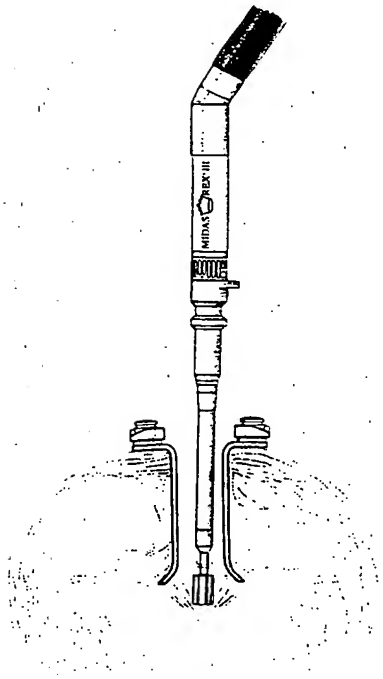


FIGURE 9

Once the decompression is completed, the bone graft receptor site is prepared. Endplate preparation consists of removing cartilage and a partial decortication, leaving a small posterior rim (*Figure 10*).

The dimensions of the corpectomy are measured precisely and the bone graft is shaped appropriately. Either autograft or allograft may be utilized. The graft is held and placed using a bone graft holder and mallet (*Figures 11 and 12*).

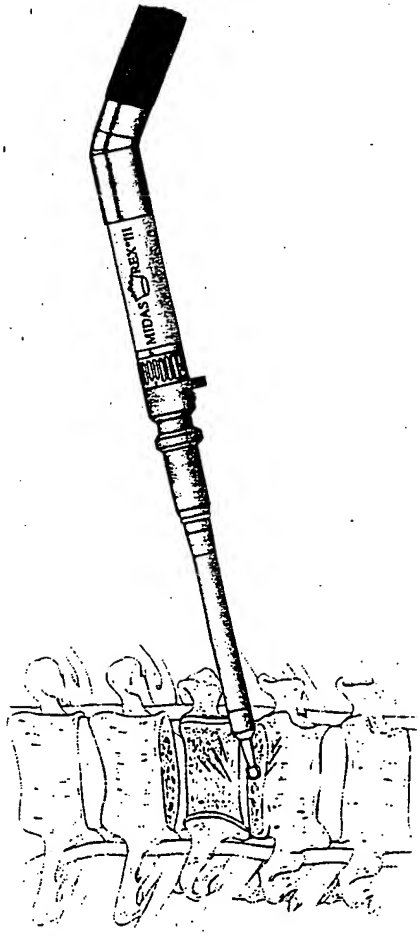


FIGURE 10

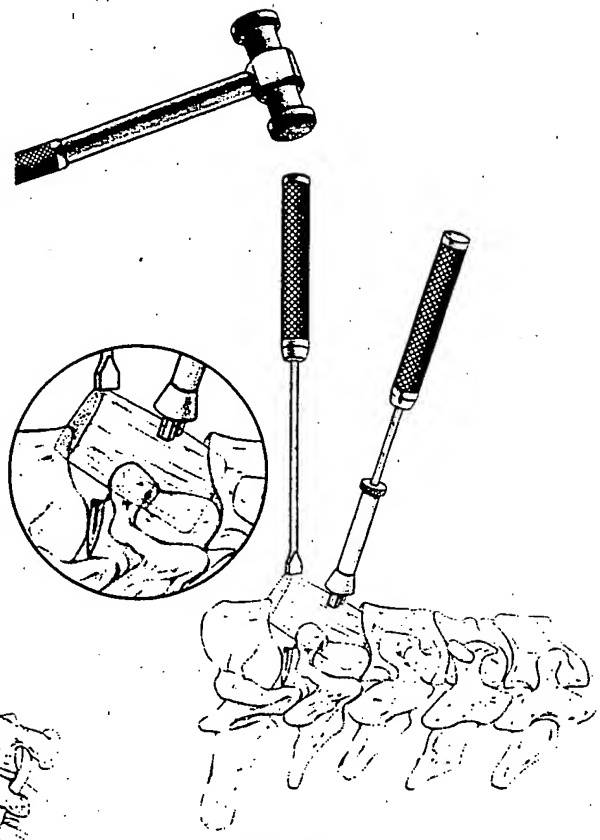


FIGURE 11

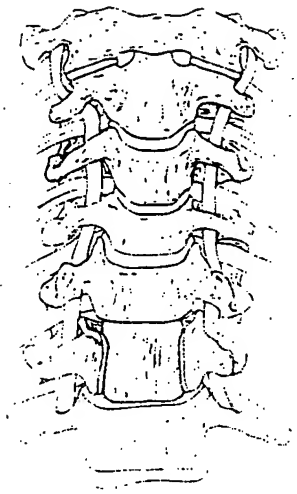


FIGURE 12

STEP 1

PLATE PLACEMENT ONLY (NO COMPRESSION)

Soft tissue and anterior osteophytes are removed from the adjacent vertebral bodies so that the plate may sit evenly on the anterior cortex. Position the plate so that the superior screw slots are close to the inferior endplate. This will ensure that as the settling occurs and the plate effectively shifts upwards, there is adequate vertebral body height to accommodate the shift (*Figure 13*). The inferior screw holes should be placed close to the superior endplate, angled away from the bone graft. This ensures good screw purchase. This will allow for placement of the fixed bone screws in the center of the vertebra. The edge of the plate should not interfere with the adjacent unfused disc spaces (*Figure 14*).

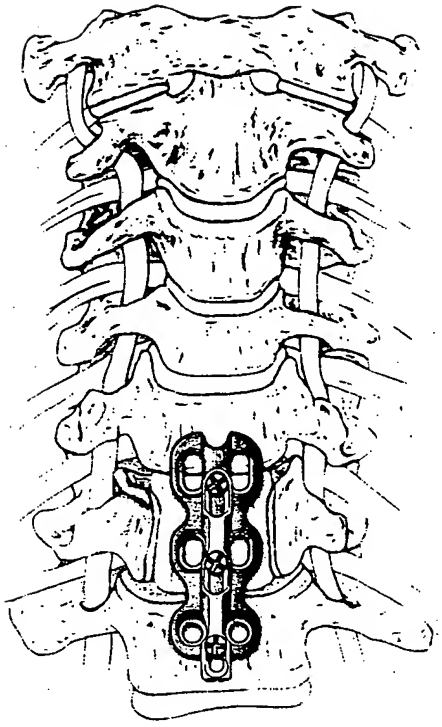


FIGURE 13

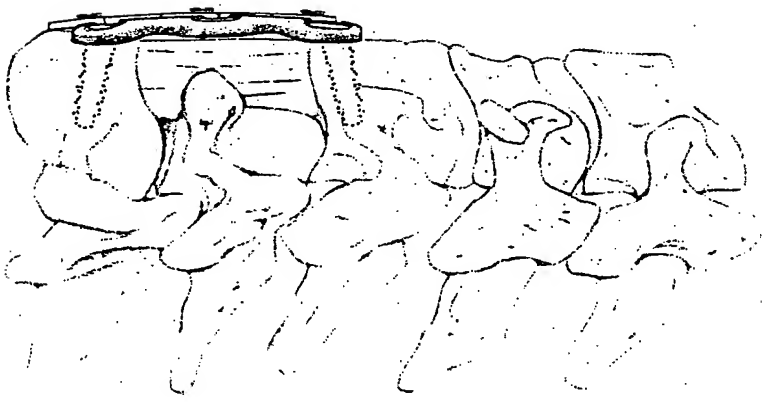


FIGURE 14

"By 'gardening' the spine; i.e. ensuring that anterior osteophytes or graft prominences are minimized, the lowest profile construct may be obtained."

– T. Zdeblick, M.D.

STEP **1A**

PLATE PLACEMENT WITH COMPRESSION OR ALIGNMENT

If the compression or alignment technique is desired, the Compression Pin should be placed with the Compression Pin Placement Template. If the Compression Pin was also used for distraction, it should remain in place for this step. Refer to the "Distraction with Planned External Compression" section on page 4.

The Compression Sleeve is placed over the Compression Pin to serve as a spacer (*Figure 15*). The plate is then nestled against the Sleeve (*Figure 16*). Care should be taken to ensure that the upper portion of the slot is positioned just superior to the graft/endplate interface.

As the plate is constrained by the Compression Sleeve, it also provides for alignment as the inferior portion of the plate is positioned.

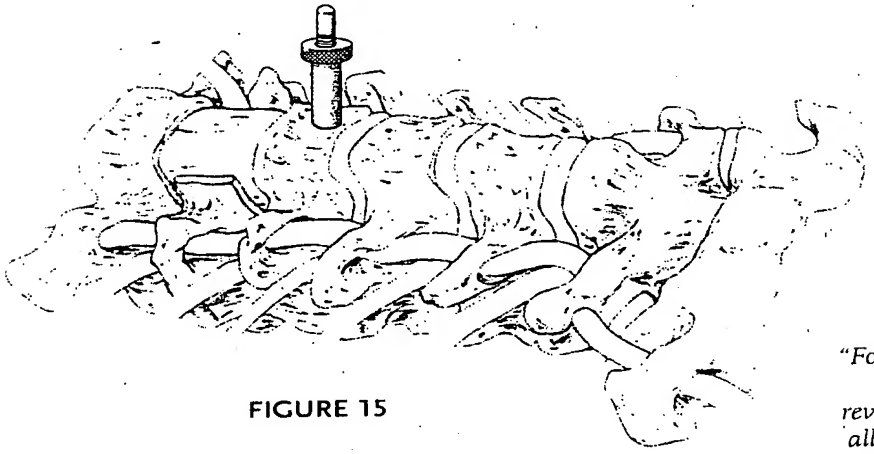


FIGURE 15

"Use of the compression pin for alignment is particularly helpful in multi level cases, when visualizing both ends of the plate simultaneously may be difficult."

– T. Zdeblick, M.D.

"For cases at the lower cervical or upper thoracic spine, the plate may be reversed, with the slot end inferior. This allows easier placement of the screws."

– T. Zdeblick, M.D.

"By placing the compression pin at the proximal end of the vertebra in the center, it ensures the plate is straight and there is sufficient room for the compression screws."

– H. Herkowitz, M.D.

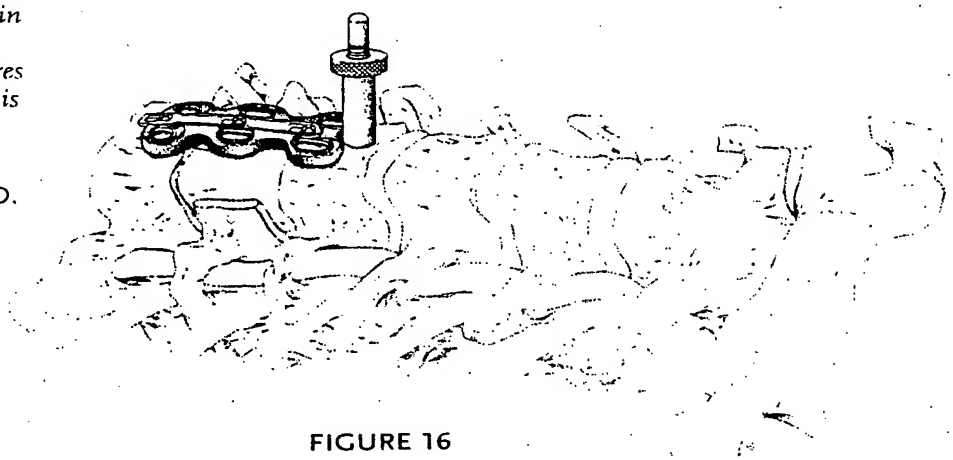


FIGURE 16

STEP 2

The PREMIER™ Anterior Cervical Plate is provided with a pre-machined lordotic curve (*Figure 17*). If required, the plate may be contoured to increase the amount of lordotic curvature (*Figure 18A*) or decrease the amount of lordotic curvature (*Figure 18B*) by using the Plate Bender. A gradual bend should be made over the entire length of the plate and abrupt changes in curvature should be avoided.

FIGURE 17

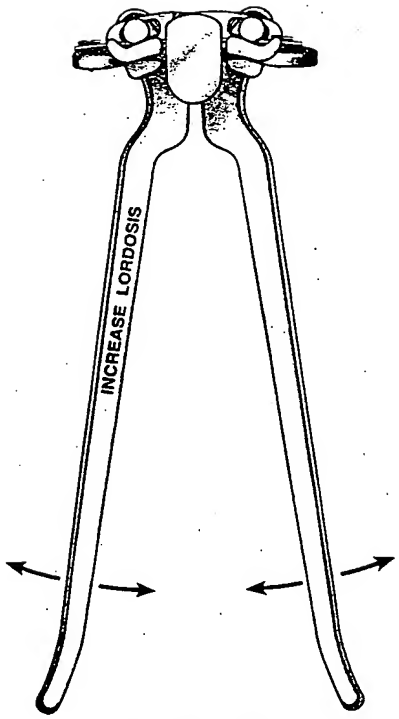


FIGURE 18A

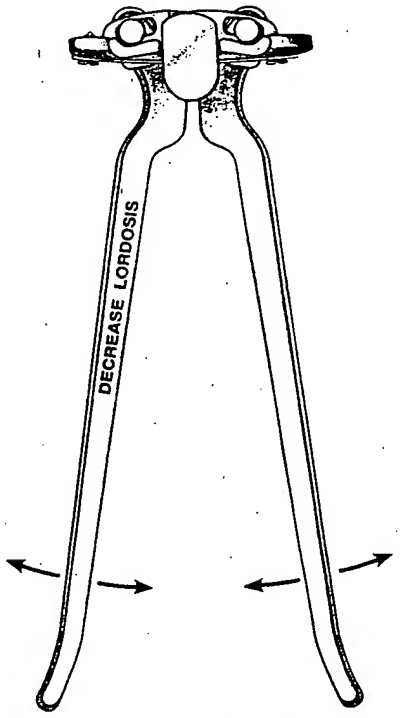


FIGURE 18B

ATTACH THE PLATE HOLDER

STEP **3**

The PREMIER™ System Plate Holder may be attached to the plate in one of the slots. The tip of the Plate Holder collapses when pressure is applied to the locking sleeve cap (*Figure 19*). Insert the collapsed tip into the slot. Releasing the pressure to the locking sleeve cap will allow the Plate Holder to securely engage the plate (*Figure 20*).

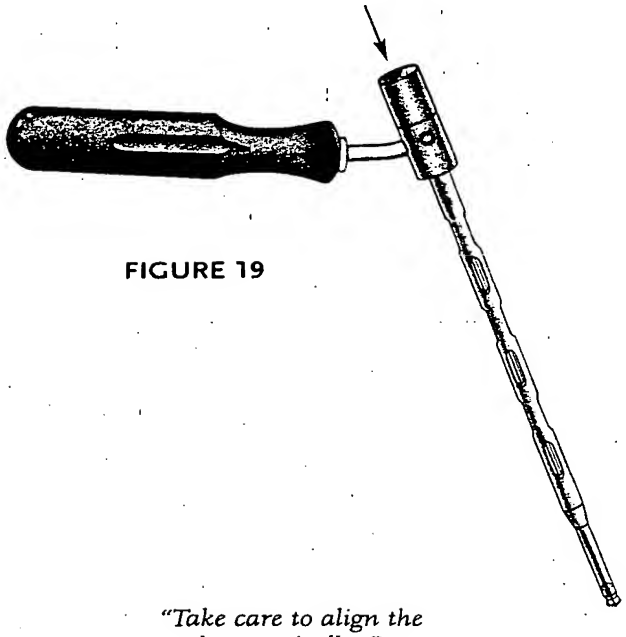


FIGURE 19

"Take care to align the plate vertically. By palpating the sternal notch, the inferior alignment can be verified."

– T. Zdeblick, M.D.

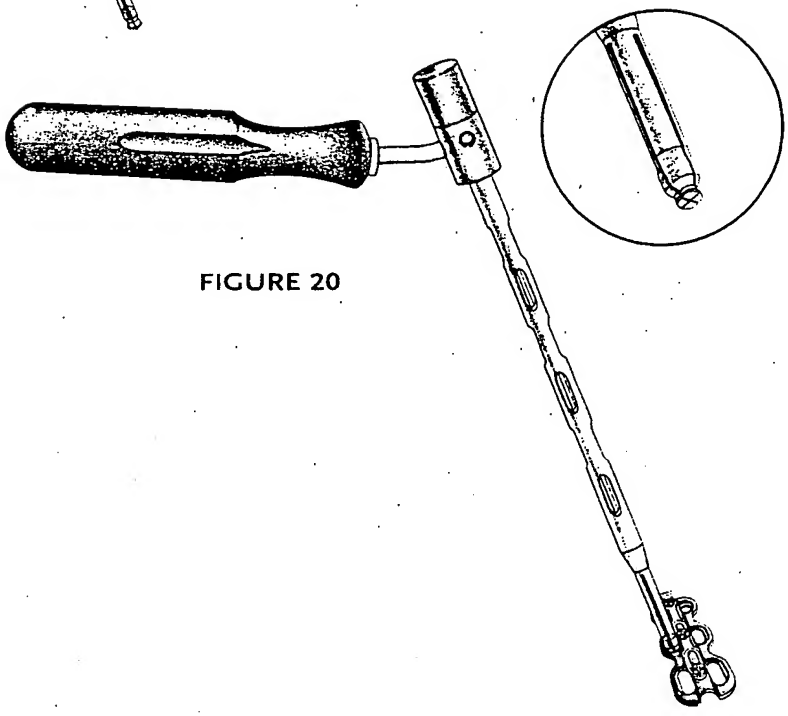


FIGURE 20

STEP **4**

After the plate length has been selected and placed on the anterior cervical spine, a Plate Holding Pin can be placed in the plate to provide temporary fi tion while drilling and placing bone screws. The pins are engaged in a Plate Holding Pin Driver to allow easy insertion into the bone (*Figure 21A*). Once seated, a Plate Holding Pin may be disengaged from the driver by applying upward pressure on the locking sleeve (*Figure 21B*).

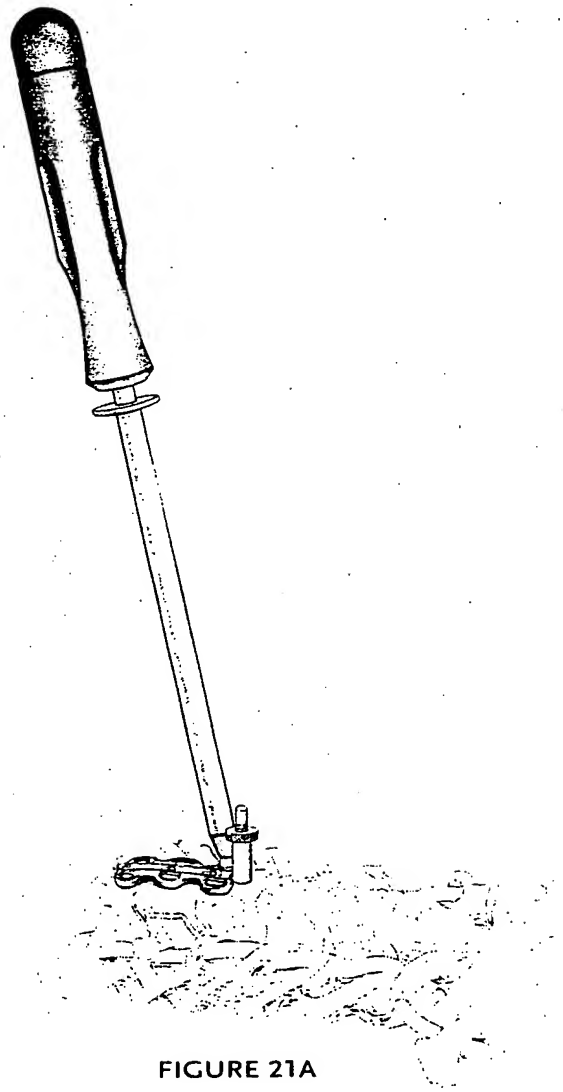


FIGURE 21A

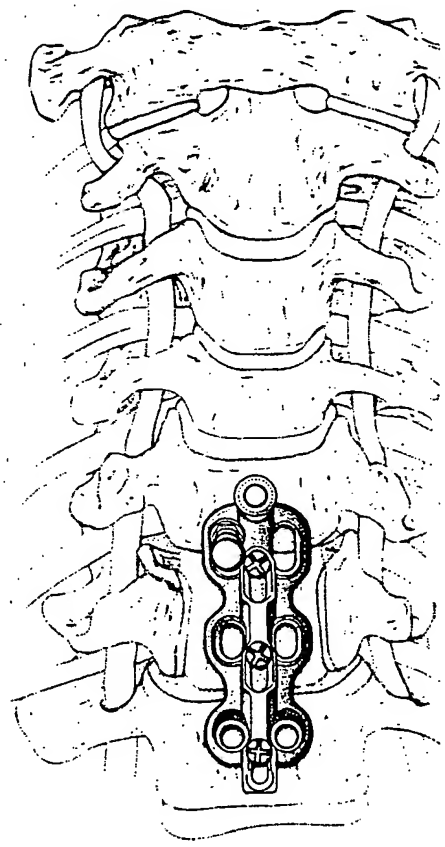
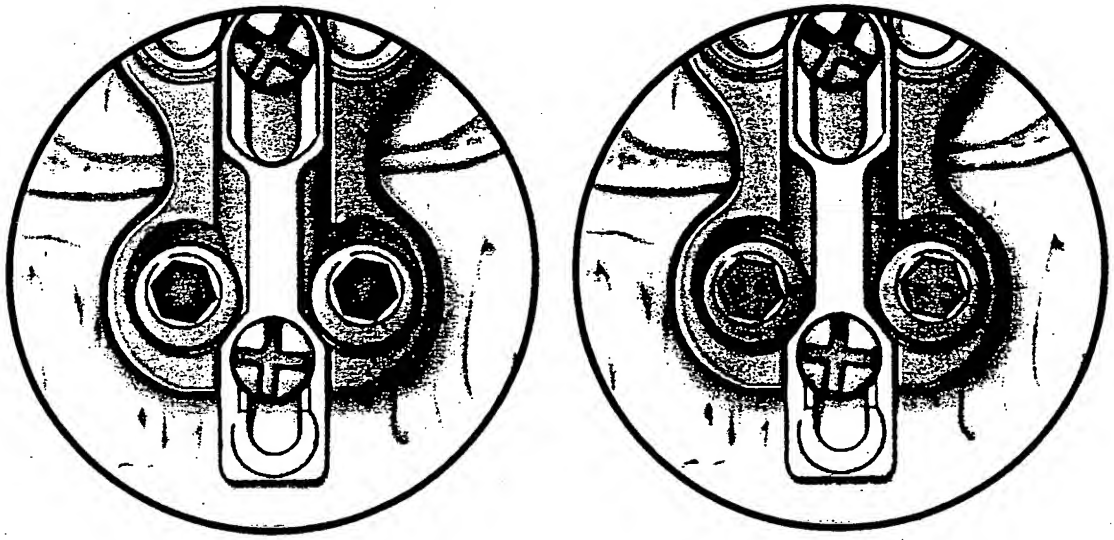


FIGURE 21B

STEP 5

The PREMIER™ System offers the surgeon the versatility of color-coded bone screws in two diameters (*Figure 22*).

The same bone screw can be utilized in the slots or the fixed holes. When the bone screws are placed in a slot, there is some intrinsic variability of placement longitudinally.



4.0mm 4.5mm

FIGURE 22

STEP 6

The Drill Guide or the Dual Drill Guide is utilized to place the bone screws in the fixed holes of the PREMIER™ plate. The Dual Drill Guide can be securely engaged in the plate by applying light downward pressure on the handle (*Figure 23*) making sure to align the drill guide in the correct 12° caudal angle (*Figure 24*).

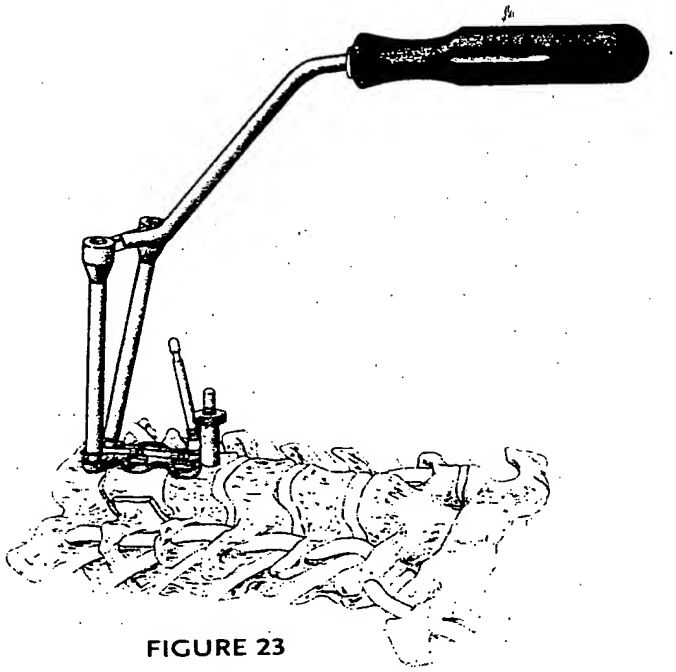


FIGURE 23

"Either the single or dual guide can be used for both the fixed holes and slots."

– H. Herkowitz, M.D.

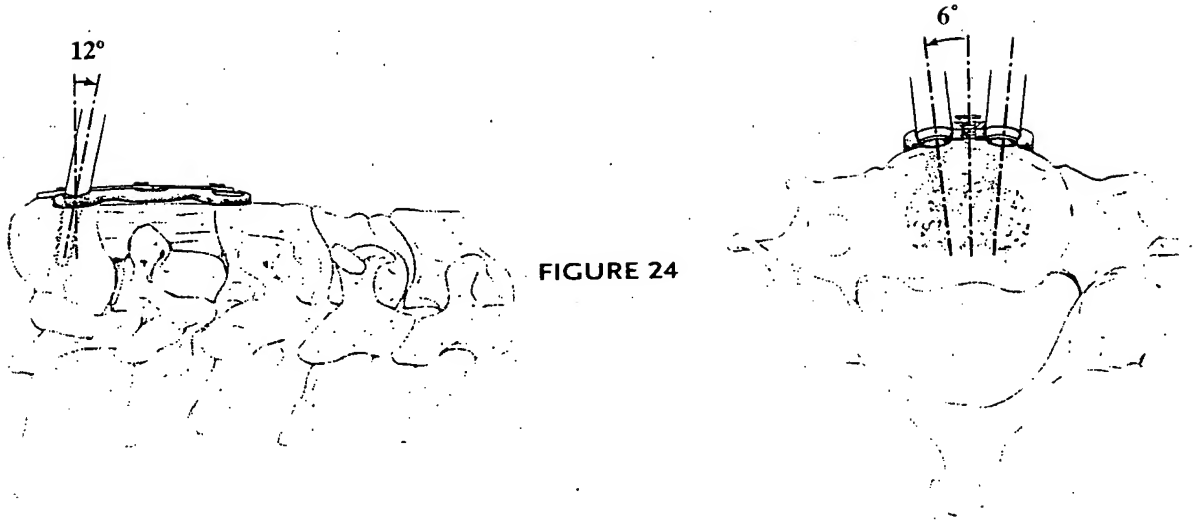


FIGURE 24

DRILL HOLES FOR FIXED SCREWS

STEP **7**

Insert the selected Drill Bit into the manual Drill Bit Handle or a power drill. A Circular Drill Bit Adaptor is provided. Place the Drill Bit into the Dual Drill Guide. Drill the screw holes using either the 13mm Drill Bit or the Adjustable Drill Bit with Adjustable Drill Stop (*Figure 25*). Screw length is determined by the depth of bone purchase required (*Figure 26*).

If required, a controlled penetration of the posterior cortex may be achieved by setting the Adjustable Stop to the appropriate depth. The Adjustable Drill Stop provides settings in 1mm increments.

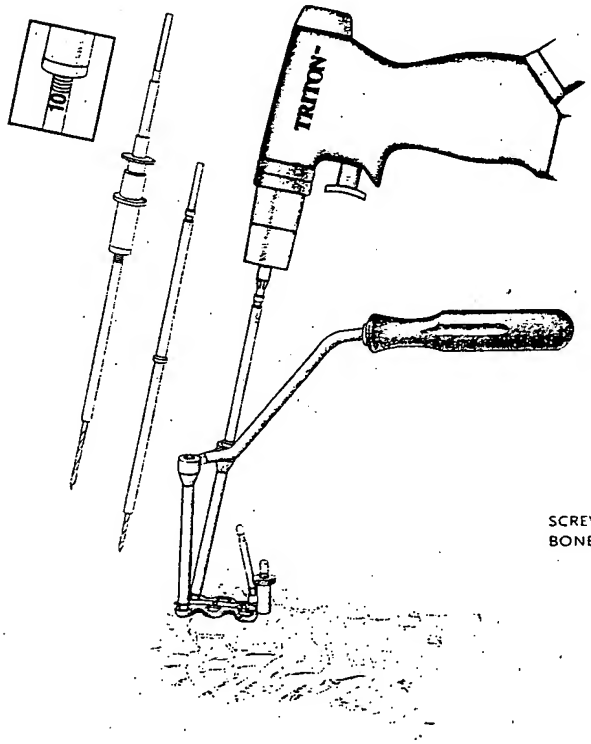


FIGURE 25

"I adjust the screw length depending on the size of the vertebra, the quality of the bone, and the diagnosis. For trauma cases, longer screws that come close to the posterior cortex are used. I use 15mm length most commonly for degenerative cases."

– T. Zdeblick, M.D.

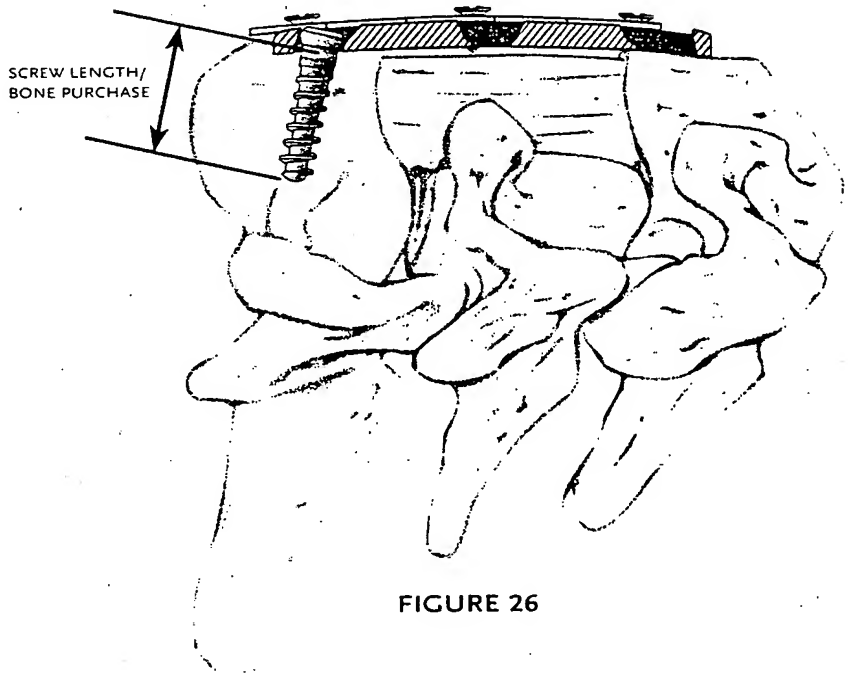


FIGURE 26

TAPPING VERTEBRAL BODIES

STEP **8**

The PREMIER™ System Bone Screws are provided self-tapping (*Figure 27*). However, if desired, the Bone Screw Tap can be inserted into the pilot hole at the same angulation that was drilled to tap the vertebral bodies (*Figure 28*).

4.0mm 4.5mm

FIGURE 27

"I find it necessary to tap when extremely hard bone is encountered."

– H. Herkowitz, M.D.

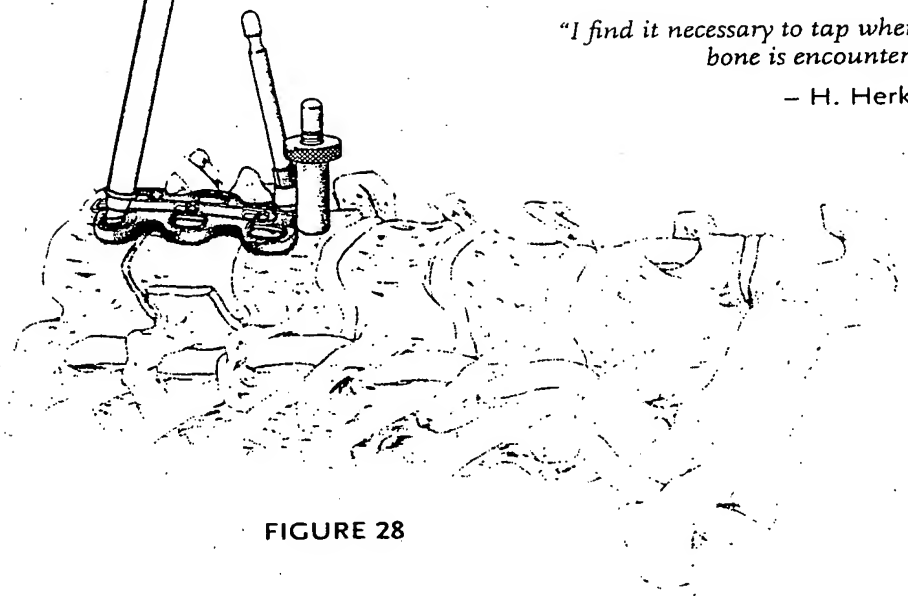


FIGURE 28

STEP 9

If required, a Depth Gage may be used to confirm the depth of the pilot hole for proper screw length. The Depth Gage works through the plate (*Figure 29*).

The appropriate screw can be verified using the Screw Gage located in the Bone Screw Block (*Figure 30*).

Insert the appropriate length bone screw through the plate using the Screwdriver and preliminarily tighten the bone screw (not final tightening). The Screwdriver has a tapered, self-holding tip to provide for easy insertion of the screw.

The preferred method of bone screw insertion is as follows:
Drill both fixed holes with the Dual Drill Guide, tap if desired, place both bone screws and incrementally tighten. Remove Plate Holding Pin with Plate Holding Pin Driver if appropriate.

Applying the bone screws to the fixed portion of the plate provides an anchor point for the compression techniques that follow.

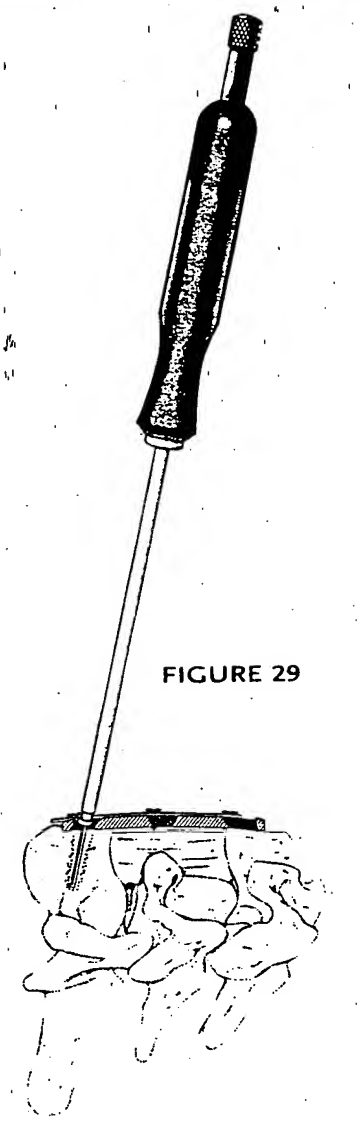


FIGURE 29

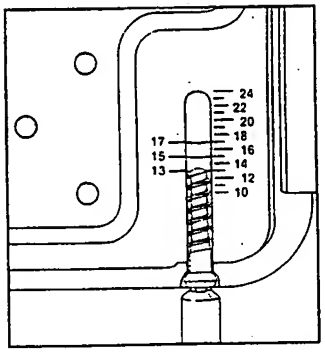


FIGURE 30

STEP
10

If desired, the external Compressor can be utilized after both fixed screws have been placed to anchor the plate. The Compressor can be utilized in the intermediate slot and with the Compression Pin to achieve up to 2mm of compression (*Figure 31*). The Compression Pin should have been placed previously with the Compression Pin Placement Template during the initial stages for distraction or during plate placement. By removing the Compression Sleeve, a space is left between the notch in the plate and the Compression Pin (*Figures 32 and 33*).

The Compressor has a ratchet to maintain the applied compression during the next step, drilling for the slot bone screws.

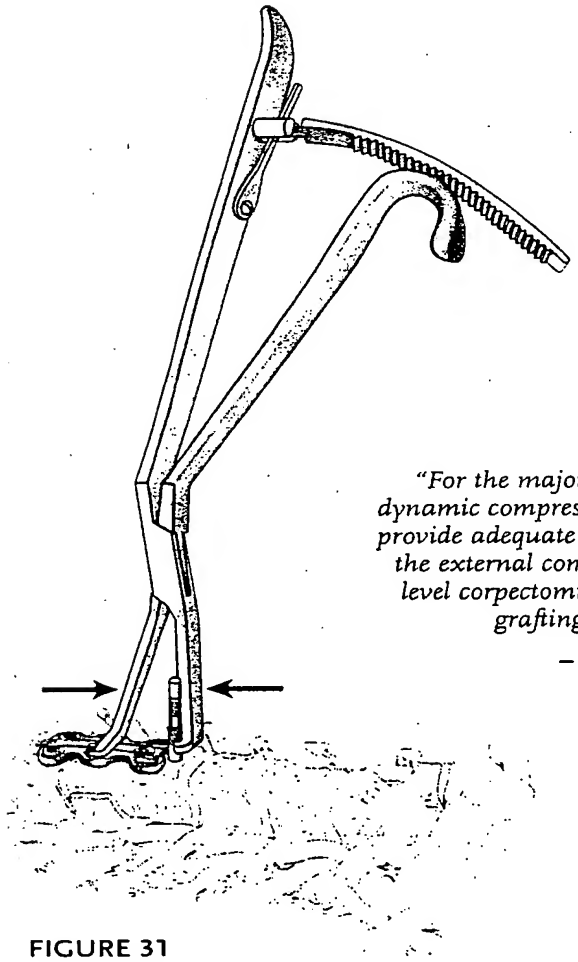


FIGURE 31

"For the majority of cases, the dynamic compression slot alone will provide adequate compression. I use the external compressor for multi level corpectomies or to correct a grafting deficit."

– T. Zdeblick, M.D.

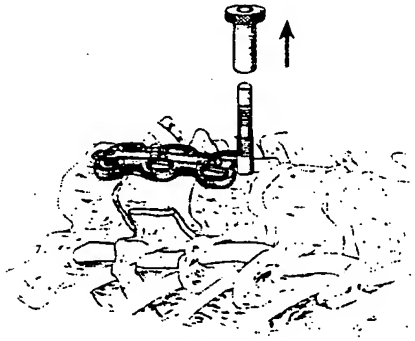


FIGURE 32

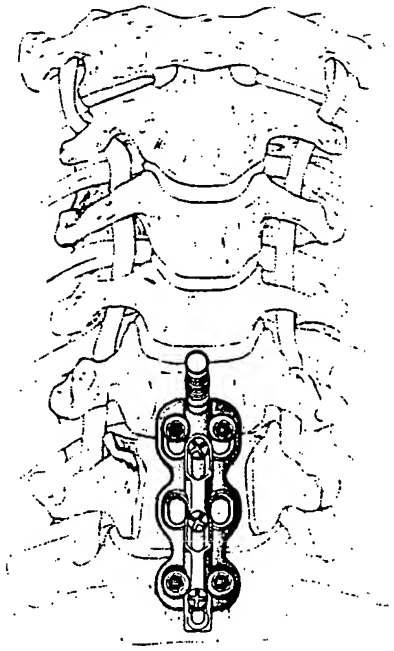


FIGURE 33

STEP 11

The PREMIER™ System provides a Single or a Dual Dynamic Slot Drill Guide for placing bone screws in the superior slots that include the dynamic compression ramp. In order to utilize the compression ramp, the Drill Guide should be placed at the top of the slot with gentle pressure pushing the guide up to the top of the ramp. Placing the bone screw in this most superior position will ensure interference with the compression ramp as the bone screw is fully tightened.

The Dynamic Slot Guides do not lock in the plate like the fixed hole guides. The unique geometry of the Drill Guide helps to reference the slot and still provides some variability longitudinally in bone screw placement *(Figure 34)*.

The dynamic slot bone screw holes should both be drilled prior to placing bone screws to ensure parallel placement of the bone screws. As described previously, the pilot holes may be tapped if desired. The optimal angulation is 12° cephalad. However, when placed in a slot, the bone screw angulation may be varied up to ±20°. The medial/lateral angulation is 6° convergent.

The superior slot bone screw should be placed as described previously with the Screwdriver *(Figure 35)*. Once the bone screws are started, the external Compressor can be removed and the Compression Pin should be removed before engaging the dynamic compression ramp. The bone screws should be incrementally tightened alternating between the two as they engage the dynamic compression ramp to ensure gradual and equal compression.

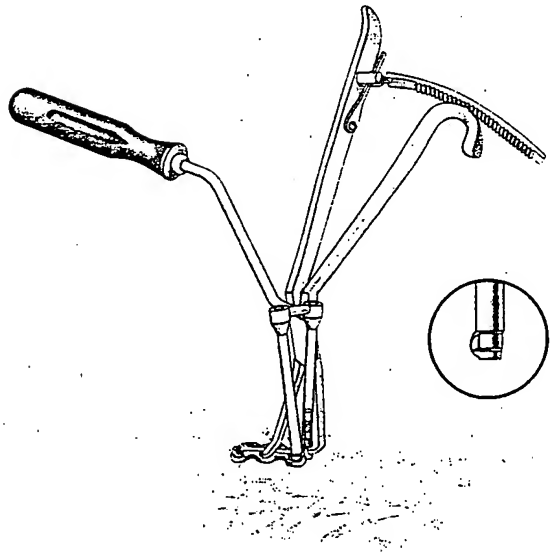


FIGURE 34

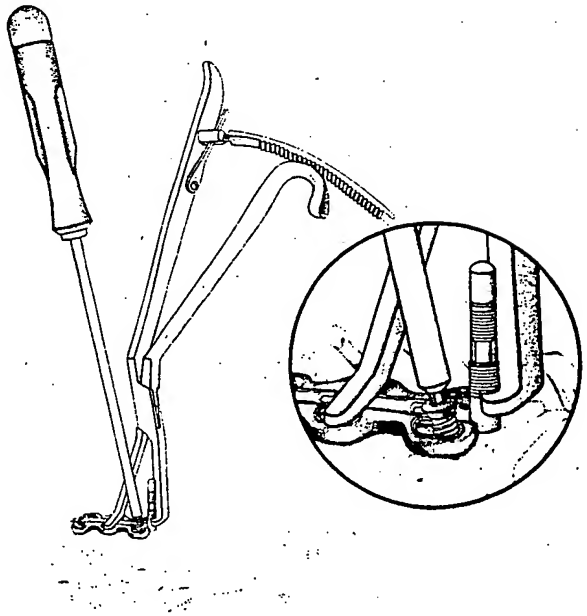


FIGURE 35

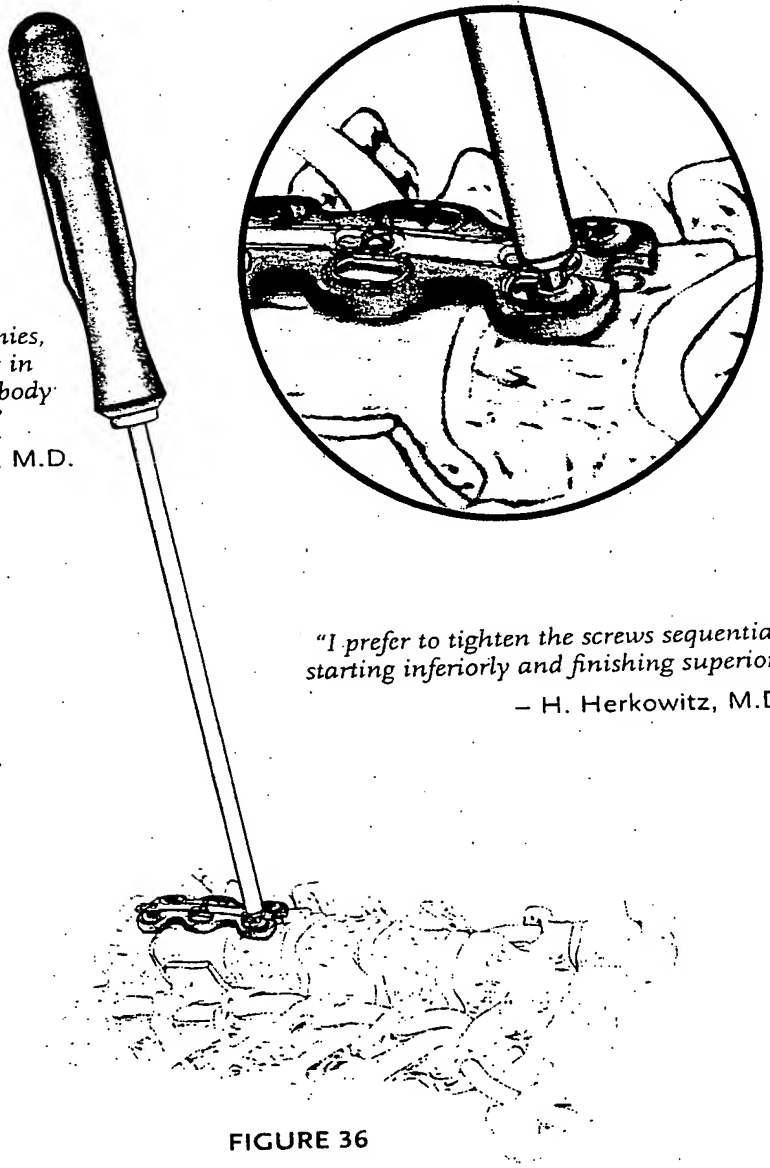
FINAL TIGHTENING OF BONE SCREWS

STEP **12**

Final tightening of all screws is done sequentially so that the plate is evenly applied to the anterior cortical surface of the spine (*Figure 36*).

"For multiple level discectomies, I typically place two screws in each intermediate vertebral body for additional fixation."

– T. Zdeblick, M.D.



"I prefer to tighten the screws sequentially, starting inferiorly and finishing superiorly."

– H. Herkowitz, M.D.

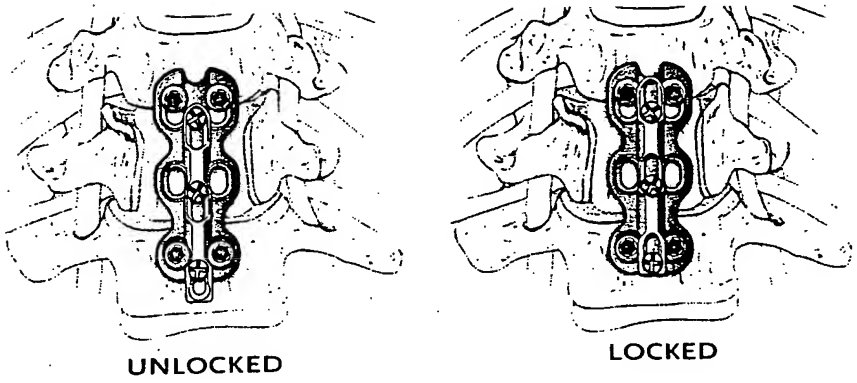
FIGURE 36

TIGHTENING OF THE ATTACHED LOCK MECHANISM

STEP **13**

All of the PREMIER™ System Lockscrews are attached to the plate in the unlocked or up position. Once all of the bone screws have been securely seated in the plate, the Lock Washer should be translated into the locked position (*Figure 37*). Once the washer is in the locked position covering the bone screw heads, the Lockscrew Driver is engaged into each Lockscrew and tightened (*Figure 38*). The lockscrew mechanism is now firmly secured.
Note: Tighten the Lockscrews starting at the inferior (fixed screw) end of the plate.

All Lockscrews within the plate must be fully engaged and tightened before the procedure is complete (*Figure 39*).



UNLOCKED LOCKED

FIGURE 37

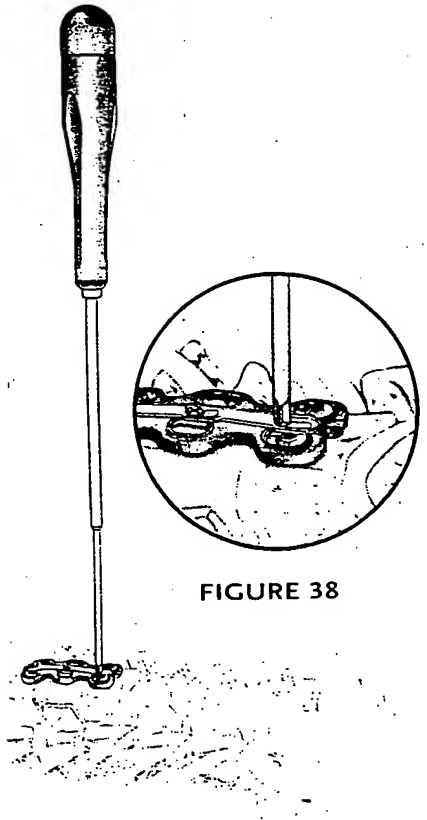


FIGURE 38

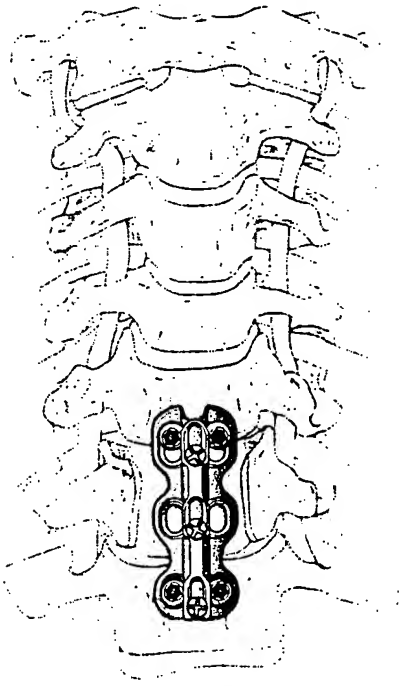


FIGURE 39

"The PREMIER™ System has improved my fusion rates on interbody as well as strut graft fusions. It has also shortened my patients' rehabilitation time, brace use and gotten my patients back to normal activities much sooner."

– H. Herkowitz, M.D.

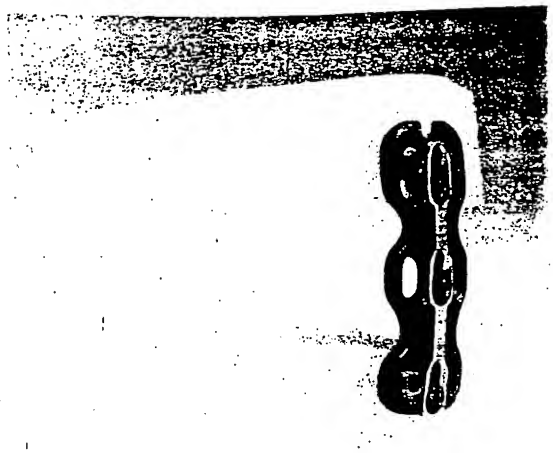


FIGURE 40

A mechanical testing standard exists to provide a basis of comparison between spinal implant assemblies. The current accepted standard of comparison is outlined in ASTM F1717 – Standard Test Methods for Static and Fatigue for Spinal Implant Constructs in a Corpectomy Model. The protocol for anterior cervical plates provides for a corpectomy model without a graft or spacer, and a 35mm spacing between inferior and superior bone screws. Plates and bone screws are assembled in the configuration shown *(Figure 40)*. In order to determine the endurance limit of a system, constructs are tested at various loads to the number of cycles that it can sustain prior to failure. The endurance limit of a construct for this protocol is the maximum load that is endured for at least 5,000,000 cycles without a failure. The PREMIER™ and other systems were subjected to the standard corpectomy compression fatigue test. All testing was performed at an independent test laboratory *(Figure 41)* and complied with the protocol previously mentioned.

RUNOUT AT 5,000,000 CYCLES IN COMPRESSIVE FATIGUE (ASTM F1717)

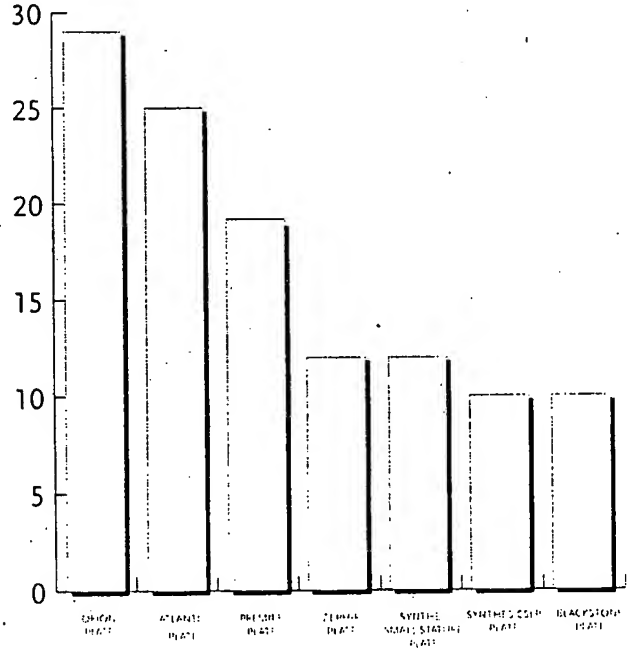


FIGURE 41

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Premier™

ANTERIOR CERVICAL PLATE SYSTEM

ANTERIOR CERVICAL PLATES

ITEM	DESCRIPTION	ITEM	DESCRIPTION
6860123	23mm Plate	6860162	62.5mm Plate
6860125	25mm Plate	6860165	65mm Plate
6860127	27.5mm Plate	6860167	67.5mm Plate
6860130	30mm Plate	6860170	70mm Plate
6860132	32.5mm Plate	6860172	72.5mm Plate
6860135	35mm Plate	6860175	75mm Plate
6860137	37.5mm Plate	6860177	77.5mm Plate
6860140	40mm Plate	6860180	80mm Plate
6860142	42.5mm Plate	6860182	82.5mm Plate
6860145	45mm Plate	6860185	85mm Plate
6860147	47.5mm Plate	6860187	87.5mm Plate
6860150	50mm Plate	6860190	90mm Plate
6860152	52.5mm Plate	6860195	95mm Plate
6860155	55mm Plate	6860200	100mm Plate
6860157	57.5mm Plate	6860205	105mm Plate
6860160	60mm Plate	6860210	110mm Plate

SELF-TAPPING CANCELLOUS SCREWS

ITEM	DESCRIPTION	ITEM	DESCRIPTION
6860010	4.0 x 10mm Self-tapping Cancellous Screw	6860016	4.0 x 16mm Self-tapping Cancellous Screw
6860011	4.0 x 11mm Self-tapping Cancellous Screw	6860017	4.0 x 17mm Self-tapping Cancellous Screw
6860012	4.0 x 12mm Self-tapping Cancellous Screw	6860018	4.0 x 18mm Self-tapping Cancellous Screw
6860013	4.0 x 13mm Self-tapping Cancellous Screw	6860019	4.0 x 19mm Self-tapping Cancellous Screw
6860014	4.0 x 14mm Self-tapping Cancellous Screw	6860020	4.0 x 20mm Self-tapping Cancellous Screw
6860015	4.0 x 15mm Self-tapping Cancellous Screw		
6860053	4.5 x 13mm Self-tapping Cancellous Screw	6860057	4.5 x 17mm Self-tapping Cancellous Screw
6860055	4.5 x 15mm Self-tapping Cancellous Screw		

INSTRUMENTS

ITEM	DESCRIPTION	ITEM	DESCRIPTION
6860402	Plate Bender	6860455	Adjustable Drill Bit, Tri-Flat
6860404	Plate Holding Pin	6860460	Adjustable Drill Stop
6860406	Plate Holding Pin Driver	6860465	Circular Bit Drill Adaptor
6860408	Plate Holder	6860468	Depth Gage
6860410	Drill Guide	6860470	Drill Bit Handle
6860412	Dual Drill Guide	6860472	4.0x13mm Tap
6860415	Dynamic Slot Drill Guide	6860482	Bone Screw Driver
6860417	Dual Dynamic Slot Drill Guide	6860484	Lockscrew Driver
6860420	Dual Guide Temporary Pin	6860500	Implant/Instrument Case
6860443	13mm Drill Bit, Tri-Flat		

COMPRESSION INSTRUMENTS

ITEM	DESCRIPTION	ITEM	DESCRIPTION
6860510	Compressor	6860525	Compression Pin Placement Template
6860516	Compression Pin	6860531	Compression Pin Driver
6860521	Compression Sleeve	6860550	Compression/Auxiliary Instrument Case

[redacted]

Intraoperative:

1. Any available instruction manuals should be carefully followed
2. At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves will cause loss of neurological function.
3. When the configuration of the bone cannot be fitted with an available temporary internal fixation device, and contouring is absolutely necessary, it is recommended that such contouring be gradual and great care be used to avoid notching or scratching the surface of the device(s). The components should not be repeatedly or excessively bent any more than absolutely necessary. The components should not be reverse bent at the same location.
4. The implant surfaces should not be scratched or notched, since such actions may reduce the functional strength of the construct.
5. Bone grafts must be placed in the area to be fused and the graft must be extended from the upper to the lower vertebrae to be fused.
6. Bone cement should not be used since this material will make removal of the components difficult or impossible. The heat generated from the curing process may also cause neurologic damage and bone necrosis.
7. Before closing the soft tissues, all of the screws should be seated onto the plate. Recheck the tightness of all screws after finishing to make sure that none has loosened during the insertion of the other screws. Also make sure the sliding washer is positioned over the heads of the bone screws and secured tightly to the plate with the set-screws. Failure to do so may result in screw loosening. **Caution:** Excessive torque on the threads may cause the threads to strip in the bone, reducing fixation.

Postoperative: The physician's postoperative directions and warnings to the patient and the corresponding patient compliance, are extremely important.

1. Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening or breakage of the components are complications which can occur as a result of excessive or early weight-bearing or excessive muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented or otherwise unable to use crutches or other such weight supporting devices. The patient should be warned to avoid falls or sudden jolts in spinal position.
2. To allow the maximum chances for a successful surgical result: the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke or consume alcohol during the bone graft healing process.
3. The patient should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
4. If a non-union develops or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. The patient must be adequately warned of these hazards and closely supervised to insure cooperation until bony union is confirmed.
The PREMIER™ Anterior Cervical Plate System implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After the spine is fused, these devices serve no functional purpose and may be removed. In most patients removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, one or more of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain. (2) Migration of implant position possibly resulting in injury. (3) Risk of additional injury from post-operative trauma. (4) Bending, loosening and/or breakage, which could make removal impractical or difficult. (5) Pain, discomfort, or abnormal sensations due to the presence of the device. (6) Possible increased risk of infection, and (7) Bone loss due to stress shielding.
6. While the surgeon must make the final decision on implant removal, it is the position of the Orthopedic Surgical Manufacturers Association that whenever possible and practical for the individual patient, bone fixation devices should be removed once their service as an aid to healing is accomplished, particularly in younger and more active patients. Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure and the difficulty of removal. Implant removal, should be followed by adequate postoperative management to avoid fracture.
7. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopaedic implants, none of the PREMIER™ Anterior Cervical Plate System components should ever be reused under any circumstances.

Packaging: Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components should be carefully checked for lack of damage prior to use. Damaged packages or products should not be used, and should be returned to MEDTRONIC SOFAMOR DANEK.

Decontamination and Cleaning: All instruments and implants must first be cleaned using established hospital methods before sterilization and introduction into a sterile surgical field. Additionally, all instruments and implants that have been previously taken into a surgical field must first be decontaminated and cleaned using established hospital methods before sterilization and reintroduction into a sterile surgical field. Cleaning and decontamination can include the use of neutral cleaners followed by deionized water rinse.

Note: Certain cleaning solutions such as those containing caustic soda, formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

Also, certain instruments may require dismantling before cleaning.

All products should be treated with care. Improper use or handling may lead to damage and possible improper functioning of the device.

Sterilization:
Unless noted otherwise on the package labeling, the PREMIER™ Anterior Cervical Plate System components are provided non-sterile. These products need to be steam sterilized by the hospital using one of the following methods:

NOTE: The following note applies to the process parameter identified with the ** below: For use of this product and instruments outside the United States, some non-U.S. Health Care Authorities recommend sterilization according to these parameters so as to minimize the potential risk of transmission of Creutzfeldt-Jakob disease, especially of surgical instruments that could come into contact with the central nervous system.

Method Cycle Temperature Exposure Time Steam Gravity 250°F (121°C) 30 Min. ** Steam Gravity 273°F (134°C) 18 Min. Steam Pre-Vacuum 270°F (132°C) 4 Min.
Remove all packaging materials prior to sterilization. Use only sterile products in the operative field. After surgery, immediately decontaminate, clean, and resterilize before handling or (if applicable) return to MEDTRONIC SOFAMOR DANEK.

Product Complaints: Any Health Care Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor, MEDTRONIC SOFAMOR DANEK. Further, if any of the implanted PREMIER™ Anterior Cervical Plate System component(s) ever "malfunctions," (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any MEDTRONIC SOFAMOR DANEK product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, fax or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

Further Information: Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If further information is needed or required, please contact:

IN USA
Director, Customer Service Division
MEDTRONIC SOFAMOR DANEK, Inc.
1800 Pyramid Place
Memphis, Tennessee 38132

Telephone Numbers:
1-800-876-3133
1-800-933-2635
or 901-396-3133
Telefax Numbers:
901-396-0356
or 901-332-3920

IN EUROPE
Telephone Number: (33) 1.49.38.80.00
Telefax Number: (33) 1.49.38.80.01

MEDTRONIC SOFAMOR DANEK International
Sofamor S.N.C.
13, rue de la Perdrix
R.C.S. Bobigny B 612 320 486
95940 TREMBLAY EN FRANCE
*authorized EC representative

[redacted]